## REMARKS

Claims 15-16 and 18-39 constitute the pending claims in the present application.

Claim 21 has been amended. No new matter has been added by this amendment.

Applicants thank Examiner for indicating the allowability of claims 15 and 16 and for withdrawing several of the rejections and objections from the previous Office Action.

### ***Claim Objections***

***Claim 22***

The objection to claim 22 as being of improper dependent form because it allegedly fails to further limit claim 21 has been maintained. Specifically, it is alleged that both antibody pairs that bind to both the alpha and beta subunits of FSH would measure total FSH and that no structural differences in the antibodies, nor any specific epitopes, have been so claimed to distinguish the antibody pairs in such a way that they would not bind total FSH.

Applicants have amended claim 21 to require that "the second antibody pair has a different specificity for at least one form of the combined alpha and beta chains of FSH from the first antibody pair." Accordingly, both pairs could not detect total FSH if one of the pairs had a different specificity for at least one of the forms in the array of FSH forms present. Support for this amendment may be found at, for example, pages 6 through 7.

Claim 22 further requires that the first antibody pair detects total FSH. Thus, it serves to further limit claim 21.

Therefore, the Applicants respectfully request withdrawal of the objection to claim 22.

### ***Claim Rejection – 35 U.S.C. §102(b) over Alfthan, et al. (1996)***

Claims 18, 26, 31 and 38 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Alfthan et al. (1996). Claims 18 and 38 require that each of the two assays use a different antibody pair, directed against a different form of the gonadotropin, that is, *two* pairs of antibodies are used in the assays. Alfthan et al. do not teach or suggest two assays using a different antibody pair directed against a different form of the gonadotropin. Rather it discloses at page 109 and 111 assays that use *one* pair of antibodies to distinguish among forms of hCG.

Accordingly, claim 18, its dependent claims 26 and 31, and claim 38 are not anticipated by Alfthan et al.

***Claim Rejection – 35 U.S.C. §102(e) over Birken et al. (U.S. Patent No. 6,521,416)***

Claims 18, 26, 31-32 and 38 have been rejected under 35 U.S.C. §102(e) as allegedly anticipated by Birken et al. (U.S. Patent No. 6,521,416). Claims 18 and 38 require that each of the two assays use a different antibody pair, directed against a different form of the gonadotropin, that is, *two* pairs of antibodies are used in the assays. In claim 18, the results of the first and second assays are compared to determine the menopausal status of said individual. In claim 38, a relative abundance of the first and second forms of the gonadotropin are dependent upon the menopausal status of the female.

Birken et al., while it teaches two assays using a different antibody pair directed against a different form of the gonadotropin, does not teach or suggest using the compared results of the assay or the relative abundance of the forms to determine the menopausal status of the female. Rather, the assays for the various forms of the gonadotropin are used in experimental methods to determine whether an assay for one particular form of a gonadotropin will be sufficient to determine the menopausal status of a female. Neither the compared results of the assays nor the relative abundance of the forms are correlated to or used to determine the menopausal status of the female. Accordingly, claim 18, its dependent claims 26 and 31-32, and claim 38 are not anticipated by Birken et al.

***Claim Rejection – 35 U.S.C. §102(b) over O'Daly et al. (U.S. Patent No. 5,391,272)***

Claim 39 has been rejected under 35 U.S.C. §102(b) as allegedly anticipated by O'Daly et al. (U.S. Patent No. 5,391,272). Claim 39 requires that the device is configured to receive and assay a sample comprising first and second forms of the same gonadotropin from a human female, a relative abundance of the first and second forms of the same gonadotropin being dependent upon the menopausal status of the female. O'Daly does not teach or suggest a device that can assay two forms of the same gonadotropin, wherein the relative abundance of the first and second forms of the same gonadotropin is dependent upon the menopausal status of the female. Accordingly, claim 39 is not anticipated by O'Daly et al.

***Claim Rejections – 35 U.S.C. §103(a)***

Claims 18-23, 24, 26-28, 29, 38, 33-37 and 39 have been rejected under 35 U.S.C. §103(a) as allegedly obvious over Berger et al. (1988) in view of EP 0736771 A1 (1995). All of the claims require that the comparative levels or relative abundance of two gonadotropin forms detected are used to determine menopausal status. A novel aspect of Applicants' invention is that comparative levels or relative abundance of two forms of the same gonadotropin may be detected by certain antibodies and may be correlated to and used to determine menopausal status. Berger does not disclose that the various FSH forms detected by the disclosed antibodies are in any way correlated with menopausal status. EP 0736771 A1 discloses a diagnostic test assembly and method for diagnosing menopausal status. However, it does not teach or suggest how the FSH forms disclosed in Berger would correlate to menopausal status nor does it suggest Berger may be combined with the disclosed invention. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. There is no teaching or suggestion in either Berger or EP 0736771 to combine the teachings. Further, the references when combined do not produce the claimed invention. In Applicants respectfully request the withdrawal of the rejection for obviousness over Berger et al. (1988) in view of EP 0736771 A1 (1995).

Claims 25 and 30 have been rejected under 35 U.S.C. §103(a) as allegedly obvious over Berger et al. (1988) in view of EP 0736771 A1 (1995) and further in view of Dullien (U.S. Patent No. 6, 174, 665). Claims 25 and 30 ultimately depend from claim 18, which was rejected as allegedly obvious over Berger et al. (1988) in view of EP 0736771 A1 (1995). As discussed above Berger et al. (1988) combined with EP 0736771 A1 (1995) does not teach or suggest the claimed invention. Dullien does not remedy that deficiency. Accordingly, the references when combined do not teach or suggest the claimed invention. Applicants respectfully request the withdrawal of the rejection for obviousness over Berger et al. (1988) in view of EP 0736771 A1 (1995) and further in view of Dullien (U.S. Patent No. 6, 174, 665).

## CONCLUSION

Any questions arising from this submission may be directed to the undersigned at (617) 832-1000.

Respectfully submitted,

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